

REMARKS

Favorable reconsideration of the subject application is respectfully requested in view of the following remarks. Claims 1, 3-4, 8 and 15 are pending in the case. With the above amendment, claims 8 and 15 have been canceled. Accordingly, claims 1 and 3-4 are now under consideration. Claims 1 and 3 have been amended to more particularly claim one aspect of Applicants' invention. It should be noted that the above amendments are made without prejudice to prosecution of any or all subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. No new matter has been added.

***Priority***

Applicants acknowledge that claims 1, 3, 4, 8, and 15, as amended, are entitled to the priority date of the parent application No. 09/910,689, filed July 20, 2001, since this is the application in which the SEQ ID NO:305 was first introduced. Applicants provide herewith a supplemental ADS reflecting this priority claim.

***Oath/Declaration***

The Action alleges that the oath or declaration is defective because it does not identify the mailing address of each inventor and the declaration does not contain a reference to priority application.

Applicants traverse the objection and note that 37 C.F.R. § 1.63(c) specifically states that addresses and priority information are required on the declaration unless they are provided in an Application Data Sheet (ADS) in accordance with 37 C.F.R. § 1.76. The present application was filed with an ADS in accordance with 37 C.F.R. § 1.76, a copy of which is included for the Examiner's convenience. Accordingly, Applicants submit that the oath and declaration are not defective and respectfully request withdrawal of the objection.

***Claims Rejections – 35 U.S.C. § 101, utility***

Claims 1, 3, 4, 8 and 15 stand rejected under 35 U.S.C. § 101 as allegedly lacking patentable utility. Specifically, the Action contends that a percentage sequence similarity of less than 100% is not deemed to reasonably support to one skilled in the art whether the biochemical activity of the claimed subject matter would be the same as that of such a similar known biomolecule. Further the Action asserts that neither the specification as filed nor any art of record discloses or suggests any property or activity for the protein compound such that another non-asserted utility would be well established for the compounds. Additionally, the Action contends that the presence of a polynucleotide in tissue that is derived from cancer cells is not sufficient for establishing a utility in diagnosis of disease in the absence of some information regarding a correlative or causal relationship between the expression of the claimed cDNA and the disease. Accordingly, the Action asserts that the claims allegedly are not supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

Applicants respectfully traverse this rejection and submit that the claimed invention is supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility. In particular, Applicants submit that the specification as filed clearly states at page 103, lines 17-25:

cDNA clones isolated in the breast subtractions BS3, BT, 2BT, BC6 and BT-Met, described above, were colony PCR amplified and their mRNA expression levels in breast tumor, normal breast and various other normal tissues were determined using microarray technology. ... The determined cDNA sequences of 131 clones determined to be over-expressed in breast tumor tissue compared to other tissues tested by a visual analysis of the microarray data are provided in SEQ ID NO: 1-35 and 42-137. (emphasis added)

Thus, given this disclosure, the skilled artisan would readily appreciate that the polynucleotide set forth in SEQ ID NO:52 is found to be over-expressed in breast tumor tissue as compared to other tissues including normal breast tissue.

The specification goes on to state at page 104, lines 8-10:

Comparison of SEQ ID NO: 52 (referred to as B854P) with sequences in the LifeSeq Gold™ database (Incyte Genomics Inc., Palo Alto, CA) revealed matches to two template sequences (nos. 228686.6 and 228686.8). The 228686 gene bin was found to consist of 4 template sequences and 28 clones. The four template sequences were aligned with SEQ ID NO: 52 using the DNASTar Seqman™ program. (emphasis added)

From this disclosure, the skilled artisan would understand that the polynucleotide set forth in SEQ ID NO:52 “matches” (*i.e.*, is 100% similar) to the two template sequences of 228686.6 and 228686.8, the polynucleotide sequences of which are set forth in SEQ ID NOS:302 and 304. Further, using the DNASTar Seqman™ sequence analysis program as described, this can easily be confirmed by the skilled artisan. For convenience, alignments made with the DNASTar Seqman™ program showing that SEQ ID NO:52 is indeed 100% identical to SEQ ID NO:302, 304, and 305 are enclosed herewith. Accordingly, the skilled artisan would readily conclude that SEQ ID NO:52 is a partial sequence of the polynucleotide set forth in SEQ ID NO:305 and, as such, these two polynucleotides would be expected to have the same expression profile. In view of this breast tumor-associated expression profile described in the specification as filed and as noted above, the skilled artisan would immediately recognize any number of utilities for the claimed polynucleotide comprising SEQ ID NO:305, for example in any of a variety of diagnostic settings for breast cancer. Applicants submit that the sequence similarity between SEQ ID NO:305 and sequences in public databases as described in the specification as filed and discussed in the Action are useful with regard to further characterization of the polynucleotide of SEQ ID NO:305 and the polypeptide it encodes. However, this information is entirely independent of its breast tumor-associated expression profile and its utility as a marker for breast cancer.

Applicants submit that the claimed invention is supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility and respectfully request withdrawal of the rejection.

***Claims Rejections – 35 U.S.C. § 112, written description***

Claims 1, 3, 4, 8 and 15 stand rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description. The claim(s) allegedly contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. In particular, the Action contends that the specification does not adequately describe a representative number of sequence consisting of at least 20 contiguous residues of the sequence provided in SEQ IDNO:305, or sequence having 75% of 90% identity with SEQ ID NO:305, or hybridizing to SEQ ID NO:305 or degenerate variants thereof.

Without acquiescing to the rejection, Applicants have amended claim 1 to remove recitation of the variant and % identity language and have canceled claim 8. It should be noted that the above amendments are made solely to expedite prosecution and without prejudice to prosecution of any or all subject matter modified and/or removed by this amendment in a related divisional, continuation and/or continuation-in-part application. Applicants urge that the above rejection has been obviated by the amendments and respectfully request its withdrawal.

***Claims Rejections – 35 U.S.C. § 112, second paragraph***

Claim 1(b) is rejected under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Action contends that claim 1(b) is indefinite because of the recitation of “complements of a sequence”.

Without acquiescing to the rejection, Applicants have amended claim 1 to recite “the sequence provided in SEQ ID NO:305, or the complement thereof”. Applicants submit that the amended claim is not indefinite and would be readily understood by the skilled artisan. Applicants submit that the rejection has been obviated and respectfully request its withdrawal.

***Claim Rejections – 35 U.S.C. § 102***

Claims 1, 3, 4, 8 and 15 stand rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Glucksmann (US 2003/0022334 A1). Specifically, the Action asserts that

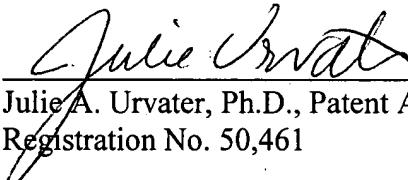
Glucksmann teaches an isolated polynucleotide with SEQ ID NO:3 which is 99% identical to an isolated polynucleotide of SEQ ID NO:305 and therefore concludes that the cited reference anticipates that claimed invention.

Without acquiescing to the rejection, and solely to expedite prosecution, Applicants have amended claim 1 and canceled claim 8 as previously noted. Accordingly, Applicants submit that the rejection has been obviated. Applicants respectfully request withdrawal of the rejection.

The Director is authorized to charge any additional fees due by way of this Amendment, or credit any overpayment, to our Deposit Account No. 19-1090.

Applicants respectfully submit that all the claims remaining in the application are now believed allowable. Favorable consideration and a Notice of Allowance are earnestly solicited.

Respectfully submitted,  
SEED Intellectual Property Law Group PLLC

  
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Enclosure:

- Postcard
- Supplemental ADS
- Copy of original ADS
- Sequence Alignments (3 pages)

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Tuesday, March 02, 2004 9:47 AM

Wilbur-Lipman DNA Alignment

Ktuple: 3; Gap Penalty: 3; Window: 20

Seq1(1>379) 491c7 seq 52 (379<-1)	Seq2(1>1518) 491c7 seq 305 (619>997)	Similarity Index 100.0	Gap Number 0	Gap Length 0	Consensus Length 379
<sup>v</sup> 370	<sup>v</sup> 360	<sup>v</sup> 350	<sup>v</sup> 340	<sup>v</sup> 330	<sup>v</sup> 320
ACCCCTGGACTCATACCTGAAAGCAGTGTTCACACCTAGCAAAATCTCCAACCAGCGCATGAACAATTTTC					<sup>v</sup> 310
ACCCCTGGACTCATACCTGAAAGCAGTGTTCACACCTAGCAAAATCTCCAACCAGCGCATGAACAATTTTC					
ACCCCTGGACTCATACCTGAAAGCAGTGTTCACACCTAGCAAAATCTCCAACCAGCGCATGAACAATTTTC					
<sup>^</sup> 620	<sup>^</sup> 630	<sup>^</sup> 640	<sup>^</sup> 650	<sup>^</sup> 660	<sup>^</sup> 670
<sup>v</sup> 300	<sup>v</sup> 290	<sup>v</sup> 280	<sup>v</sup> 270	<sup>v</sup> 260	<sup>v</sup> 250
TACATCACAAACGACCTGGTTTCAAATTCAAGCTCTCAAGGCCAATCTTTCTAAATTAAACCAAGAACT					<sup>v</sup> 240
TACATCACAAACGACCTGGTTTCAAATTCAAGCTCTCAAGGCCAATCTTTCTAAATTAAACCAAGAACT					
TACATCACAAACGACCTGGTTTCAAATTCAAGCTCTCAAGGCCAATCTTTCTAAATTAAACCAAGAACT					
<sup>^</sup> 690	<sup>^</sup> 700	<sup>^</sup> 710	<sup>^</sup> 720	<sup>^</sup> 730	<sup>^</sup> 740
<sup>v</sup> 230	<sup>v</sup> 220	<sup>v</sup> 210	<sup>v</sup> 200	<sup>v</sup> 190	<sup>v</sup> 180
TCATCAGTTCACAGAGAAAGTAATCCAGGACCGGAAGGAGTCTCTTAAGGATAAGCTAAAACAAGATACT					<sup>v</sup> 170
TCATCAGTTCACAGAGAAAGTAATCCAGGACCGGAAGGAGTCTCTTAAGGATAAGCTAAAACAAGATACT					
TCATCAGTTCACAGAGAAAGTAATCCAGGACCGGAAGGAGTCTCTTAAGGATAAGCTAAAACAAGATACT					
<sup>^</sup> 760	<sup>^</sup> 770	<sup>^</sup> 780	<sup>^</sup> 790	<sup>^</sup> 800	<sup>^</sup> 810
<sup>v</sup> 160	<sup>v</sup> 150	<sup>v</sup> 140	<sup>v</sup> 130	<sup>v</sup> 120	<sup>v</sup> 110
ACTCAGAAAAGGCCTGGGATTTCTGGACATACTTTGAGTGCCAAAGCGAAAACACCAAAGATTCT					<sup>v</sup> 100
ACTCAGAAAAGGCCTGGGATTTCTGGACATACTTTGAGTGCCAAAGCGAAAACACCAAAGATTCT					
ACTCAGAAAAGGCCTGGGATTTCTGGACATACTTTGAGTGCCAAAGCGAAAACACCAAAGATTCT					
<sup>^</sup> 830	<sup>^</sup> 840	<sup>^</sup> 850	<sup>^</sup> 860	<sup>^</sup> 870	<sup>^</sup> 880
<sup>v</sup> 90	<sup>v</sup> 80	<sup>v</sup> 70	<sup>v</sup> 60	<sup>v</sup> 50	<sup>v</sup> 40
CTGAAGCAGATCTCCAGGCTGAAGTGAAACGTTCATGTTGCAGGACATGACACCACATCCAGTGCTAT					<sup>v</sup> 30
CTGAAGCAGATCTCCAGGCTGAAGTGAAACGTTCATGTTGCAGGACATGACACCACATCCAGTGCTAT					
CTGAAGCAGATCTCCAGGCTGAAGTGAAACGTTCATGTTGCAGGACATGACACCACATCCAGTGCTAT					
<sup>^</sup> 900	<sup>^</sup> 910	<sup>^</sup> 920	<sup>^</sup> 930	<sup>^</sup> 940	<sup>^</sup> 950
<sup>v</sup> 20	<sup>v</sup> 10				<sup>^</sup> 960
CTCCTGGATCCTTACTGCTTGGCAAAGT					
CTCCTGGATCCTTACTGCTTGGCAAAGT					
CTCCTGGATCCTTACTGCTTGGCAAAGT					
<sup>^</sup> 970	<sup>^</sup> 980	<sup>^</sup> 990			

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Wilbur-Lipman DNA Alignment

Ktuple: 3; Gap Penalty: 3; Window: 20

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Seq1(1>1598) 491c7 seq 302 (692<312)	Seq2(1>379) 491c7 seq 52 (1>379)	Similarity Index 100.0	Gap Number 0	Gap Length 0	Consensus Length 379
✓690	✓680	✓670	✓660	✓650	✓640
ACTTTGCCAAGCAGTAAAGGATCCAGGAGATAGCACTGGATGTGGTGTATGTCCTGCAAACATGAACGT					✓630
ACTTTGCCAAGCAGTAAAGGATCCAGGAGATAGCACTGGATGTGGTGTATGTCCTGCAAACATGAACGT					
ACTTTGCCAAGCAGTAAAGGATCCAGGAGATAGCACTGGATGTGGTGTATGTCCTGCAAACATGAACGT					
▲10	▲20	▲30	▲40	▲50	▲60
▲70					
✓620	✓610	✓600	✓590	✓580	✓570
TTTCACTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGTGTTCGCTTTGGCACTCAAAAGTATG					✓560
TTTCACTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGTGTTCGCTTTGGCACTCAAAAGTATG					
TTTCACTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGTGTTCGCTTTGGCACTCAAAAGTATG					
▲80	▲90	▲100	▲110	▲120	▲130
▲140					
✓550	✓540	✓530	✓520	✓510	✓500
TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTGTTTAGCTTATCCTTAAGAGACTCCTTCCGGT					✓490
TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTGTTTAGCTTATCCTTAAGAGACTCCTTCCGGT					
TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTGTTTAGCTTATCCTTAAGAGACTCCTTCCGGT					
▲150	▲160	▲170	▲180	▲190	▲200
▲210					
✓480	✓470	✓460	✓450	✓440	✓430
CCTGGATTACTTCTCTGTGAAC TGATGAAGTTCTGGTTAAATTAGAAAAGATTGGCCTTGAGAGCT					✓420
CCTGGATTACTTCTCTGTGAAC TGATGAAGTTCTGGTTAAATTAGAAAAGATTGGCCTTGAGAGCT					
CCTGGATTACTTCTCTGTGAAC TGATGAAGTTCTGGTTAAATTAGAAAAGATTGGCCTTGAGAGCT					
▲220	▲230	▲240	▲250	▲260	▲270
▲280					
✓410	✓400	✓390	✓380	✓370	✓360
GAATTTGAAAACCAGGT CGTTGTGATGTAGAAAATTGTTCATGCGCTGGTTGGAGATT TGCTAAGGTTG					✓350
GAATTTGAAAACCAGGT CGTTGTGATGTAGAAAATTGTTCATGCGCTGGTTGGAGATT TGCTAAGGTTG					
GAATTTGAAAACCAGGT CGTTGTGATGTAGAAAATTGTTCATGCGCTGGTTGGAGATT TGCTAAGGTTG					
▲290	▲300	▲310	▲320	▲330	▲340
▲350					
✓340	✓330	✓320			
AACACTGCTTCAGGTATGAGTCCAGGGT					
AACACTGCTTCAGGTATGAGTCCAGGGT					
AACACTGCTTCAGGTATGAGTCCAGGGT					
▲360	▲370				

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Wilbur-Lipman DNA Alignment

Ktuple: 3; Gap Penalty: 3; Window: 20

Seq1(1>2015) 491c7 seq 304	Seq2(1>379) 491c7 seq 52	Similarity Index	Gap Number	Gap Length	Consensus Length
(1113<733)	(1>379)	100.0	0	0	379
v1110	v1100	v1090	v1080	v1070	v1060
ACTTTGCCAAGCAGTAAAGGATCCAGGAGATAGCACTGGATGTGGTGT	CATGTCCTGCAAACATGAACGT		v1050		
ACTTTGCCAAGCAGTAAAGGATCCAGGAGATAGCACTGGATGTGGTGT	CATGTCCTGCAAACATGAACGT				
ACTTTGCCAAGCAGTAAAGGATCCAGGAGATAGCACTGGATGTGGTGT	CATGTCCTGCAAACATGAACGT				
^10	^20	^30	^40	^50	^60
v1040	v1030	v1020	v1010	v1000	v990
TTTCACCTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	v980
TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	
TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	TTTCAGCCTGGAGATCTGCTTCAGAGAAATCTTGGT	
^80	^90	^100	^110	^120	^130
v970	v960	v950	v940	v930	v920
TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	TTAGCTTATCCTTAAGAGACTCCTTCCGGT	TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	TTAGCTTATCCTTAAGAGACTCCTTCCGGT	TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	v910
TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	TTAGCTTATCCTTAAGAGACTCCTTCCGGT	TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	TTAGCTTATCCTTAAGAGACTCCTTCCGGT	TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	
TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	TTAGCTTATCCTTAAGAGACTCCTTCCGGT	TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	TTAGCTTATCCTTAAGAGACTCCTTCCGGT	TCCAGAAAATCCCAGCGCCTTTCTGAGTAGTATCTTGGT	
^150	^160	^170	^180	^190	^200
v900	v890	v880	v870	v860	v850
CCTGGATTACTTCTCTGTGAAC	TGATGAAGTTCTGGTAAATTAGAAAAGATT	CCTGGATTACTTCTCTGTGAAC	TGATGAAGTTCTGGTAAATTAGAAAAGATT	CCTGGATTACTTCTCTGTGAAC	v840
CCTGGATTACTTCTCTGTGAAC	TGATGAAGTTCTGGTAAATTAGAAAAGATT	CCTGGATTACTTCTCTGTGAAC	TGATGAAGTTCTGGTAAATTAGAAAAGATT	CCTGGATTACTTCTCTGTGAAC	
CCTGGATTACTTCTCTGTGAAC	TGATGAAGTTCTGGTAAATTAGAAAAGATT	CCTGGATTACTTCTCTGTGAAC	TGATGAAGTTCTGGTAAATTAGAAAAGATT	CCTGGATTACTTCTCTGTGAAC	
^220	^230	^240	^250	^260	^270
v830	v820	v810	v800	v790	v780
GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	CATGCGCTGGTGGAGATT	GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	CATGCGCTGGTGGAGATT	GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	v770
GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	CATGCGCTGGTGGAGATT	GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	CATGCGCTGGTGGAGATT	GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	
GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	CATGCGCTGGTGGAGATT	GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	CATGCGCTGGTGGAGATT	GAATTTGAAAACCAGGTCGTTGTGATGTAGAAAATTGTT	
^290	^300	^310	^320	^330	^340
v760	v750	v740			
AACACTGCTTCAGGTATGAGTCCAGGGT					
AACACTGCTTCAGGTATGAGTCCAGGGT					
AACACTGCTTCAGGTATGAGTCCAGGGT					
^360	^370				